In its most recent report, the President’s Commission on Bioethics discusses the U.S. regulatory framework for reproductive technologies. We offer three perspectives, from the U.S. and from abroad.

Something Old and Something New

BY KATHY HUDSON

The President’s Council on Bioethics has explored a range of reproductive technologies over the last two years. It has now issued its findings and recommendations in a new report, *Reproduction & Responsibility: The Regulation of New Biotechnologies*. The report raises some important issues, but also overlooks some important concerns while overemphasizing others that are less immediate.

The report begins by laying out the “human goods” at stake. For some of these goods, such as protecting the health and well-being of children born with the aid of new reproductive technologies, the report endeavors to provide targeted recommendations. On others, however, the report is largely silent. To be sure, some of these goods may be less amenable to specific actions. But others, such as protecting the privacy of medical and genetic information and preventing inequality and discrimination based on genetic information, are ripe for policy and regulatory action based on a robust ethical and policy analysis. Regrettably, the report merely enumerates privacy and nondiscrimination as important goods, then dismisses them from consideration because these issues “have been the focus of professional self-regulation and legislative enactments.” In truth, the nation has as yet been unable to enact legislation to protect against genetic discrimination, and clear and strong recommendations from the council on this matter would have been of considerable value in spurring legislative action.

Although the title of the report suggests its subject is “new biotechnologies,” the focus is actually split between the now quarter-of-a-century old technology of in vitro fertilization and some “new” technologies that are, as yet, only imagined. What links the old and futuristic technologies considered in this report is that they all involve the creation or manipulation of the human embryo outside a woman’s womb.

This presents another gap. Technologies involving the creation and manipulation of human embryos in the laboratory do indeed raise important safety and ethical concerns, yet other biotechnologies that are in widespread and growing use in reproduction, namely prenatal and carrier testing, are not considered at all. Millions of prospective parents each year are using genetic testing to find out about their own genetic makeup or that of their developing fetus and to make profound reproductive decisions. For many, planning for and building a family is the first time they must confront the many issues that attend genetic testing. As the number, type, and complexity of genetic tests continues to grow, so too will the questions that parents, prospective parents, and society must face regarding safety, equity, discrimination, human worth, and the meaning of a good life.

The report shines klieg lights on some issues in reproductive medicine that have not received enough attention. In particular, the report focuses attention on assisted-reproduction technology (ART) and the need for more data regarding the long-term health effects of ART on women and children. Like the council, I am deeply troubled that, with greater than 1 percent of all newborns in the United States getting their start with ART, we in the United States have done very little to assess the health and developmental outcomes of this growing segment of our population. When prospective parents are making decisions about bringing a child into the world and how they will go about doing it, they should have access to complete and accurate information on the risks and benefits to themselves and their future child. Thus I support the report’s recommendations that a federally funded longitudinal study be undertaken to assess the impact of

ART on children. The council also recommends that the planned NIH National Children's Study be used as a vehicle for collecting this data. This proposal is initially tantalizing because of its simplicity and minimal relative cost, but the NIH study would be unlikely to provide much meaningful data on ART children because the numbers will simply be too small. One would predict that 1,000 of the 100,000 children enrolled in the study would be conceived with the aid of ART. But 1,000 is simply too few to reveal increases in anomalies such as Beckwith-Wiedemann syndrome, which normally occurs in only one in 15,000 births. (The ART Children's Health Study that the Genetics and Public Policy Center has undertaken in conjunction with the American Academy of Pediatrics and the American Society for Reproductive Medicine will, we hope, provide the necessary foundation to design the sound prospective studies called for by the council).

The report also spends significant time analyzing (and calling for prohibitions of) several rather freakish processes that are at present largely in the realm of science fiction. The possible novel life-forms posited by the council—animal-human hybrids, cross-species gestation, and chimeric embryos, to name a few—would give any reasonable person the heebie-jeebies, and no one in good conscience could argue that these are activities that we should pursue at the present time. But here, too, one may wonder about the practical relevance of this domain of the report’s inquiry. Moreover, I fear that this focus on the freakish will convey a distorted, falsely negative impression of biomedical research and the reproductive medicine community as a whole, notwithstanding the report’s laudatory remarks concerning the ethics and standards of the majority of scientists.

Policymakers have shown little interest in the recommendations of governmental ethics advisory committees: while past commissions have issued myriad recommendations, only a handful have been translated into concrete action, as measured by new legislation or regulations or the pursuit of new research priorities. To be sure, the value of bioethics commissions lies not only in how many new laws are passed, but also in the manner and scope of their inquiry and the public discourse that they foster. As noted repeatedly in the report and indeed, in the charter of the council, the charge of this commission extends beyond merely receiving testimony from organized stakeholder groups; it is also to provide “a forum for a national discussion of bioethical issues.” Indeed, the report recognizes that many of the problems it identifies “demand serious public deliberation” and that certain recommendations would be premature if made without broad-based public input. Yet despite the aspirations of the mission statement, the council and its predecessor bodies have not been given the tools to conduct the broad-based public discussion that is needed here.

As one who has closely followed the progress of the council’s deliberations, I have witnessed the metamorphosis that this report has undergone. The scope of the document’s inquiry has expanded and its analysis is far more nuanced and balanced than were its early drafts. This change is largely due, I believe, to the council’s diligent efforts to solicit input from a wide variety of stakeholders, including representatives of the infertility advocacy and reproductive medicine communities, as well as recognized legal and government experts.

Since its formation, the council has been the subject of extraordinary criticism about its composition and conduct. This report suggests that such concerns may have been overblown. Recent changes to the membership of the council have renewed criticism that the council is dangerously unbalanced. One can only hope that those concerns are likewise overblown, and that the council will continue to seek diverse points of view.

Paradoxes and Political Problems: The U.S. Approach to ART as Seen from the U.K.

BY SANDY THOMAS

Viewed from a country where the development and application of new assisted reproductive technologies (ART) are primarily regulated by a single statutory body, the U.S. approach seems something of a patchwork. A complex mix of federal, state, indirect governmental, and non-governmental regulation govern research and practice in ART. The President’s Council on Bioethics’ recent report, Reproduction and Responsibility, acknowledges and explains the complexity in the context of the U.S. legal landscape. In doing so,
it concludes that the U.S. regulatory framework lacks coherence and that much within it is unenforceable. It argues that more needs to be done to protect consumers, particularly women who receive ART and children born with its help.

The report takes as its starting point the confluence of developments in reproductive biology, developmental biology, and human genetics, against a background of the growing use of genetic screening and embryo selection. Since technologies that deal with human reproduction are closely linked to the debate on abortion, their use is fraught with ethical and political difficulties. In addition, the deep disagreement in the United States about the degree of respect owed to in vitro embryos has created a strong disincentive for regulation, and is one of the main reasons for what is described as the U.S.’s laissez-faire approach. The report unpacks the regulatory framework, starting with federal legislation. In clinical practice, there is only one federal statute relating to ART, which primarily provides consumers with data about success rates of fertility clinics. Failing to report does not, however, attract penalties. With regard to state legislation, few state laws appear to bear directly on the use of ART. Rather, the report concludes, state oversight of ART is achieved indirectly, primarily by the licensure and certification of practitioners. The FDA is described as having broadly abstained from regulating ART, but some notable exceptions are highlighted, including a requirement for an IND (investigational new drug) for the transfer of ooplasm and asserting the same for the transplantation of cloned embryos. Finally, the importance of professional guidance, such as the standards propounded by the American Society for Reproductive Medicine (ASRM) published in conjunction with the Society for Assisted Reproductive Technology (SART), is acknowledged, but with the caveat that enforceability is weak.

The report adds some welcome insights into the context that has formed the backdrop for regulation of one of the most contentious technologies—the derivation and use of embryonic stem cells. The statutory ban imposed by Congress to ban the former but allow the debate to continue about the latter. Taken with other recommendations in the report, which among other things would prohibit research on embryos that are older than ten to fourteen days, these members believe that the “slippery slope” arguments against research on embryonic stem cells would be addressed. However, five other members emphasise that because the report is silent on whether research on embryos before this time should be permissible at all, the Council does not endorse the destruction of human embryos at any stage of their development. The political stakes are high: the House of Representatives has passed a bill banning creation of cloned embryos for any purpose. If enacted, it would prohibit the derivation and use of cloned embryonic stem cells.

The report suggests a series of interim measures to strengthen existing legislation and provide safeguards. It acknowledges that not all of the ethical issues raised by technologies such as pre-implantation genetic diagnosis (PGD) are amenable to legislation, but it argues convincingly for significantly greater monitoring. The dearth of U.S. data about the use of PGD is worrying. The fact that the report falls short of making recommendations aimed at evening out some of the more polarized arguments about the ethics of new ART illustrates the very deep divisions underlying their development.

Horror regulationum

BY HENK TEN HAVE

The advance of new technologies has been rapid at the intersection of assisted reproduction, human genomic knowledge and technique, and human embryo research. These technologies also have had and promise to continue to have a major impact on the well-being of individuals and of society as a whole. All societies are faced with questions about how to deal with their social and ethical consequences. The latest report from the President’s Council on Bioethics carefully out-

lines the many values and ideals that are at stake. Because the technologies discussed in the report all involve the creation of another human being, concern for the health, safety, and well-being of the children born with their aid is the basic moral issue. In many countries, the major question to be addressed is: How to regulate new technologies?

The report is the product of two years of reflection and deliberation. The report first of all presents a diagnostic overview of all current oversight and regulatory activities in relation to biotechnologies. It also provides an excellent overview of the moral problems involved, going beyond the usual pragmatic approach of delineating specific ethical issues raised in connection to particular technologies. Technologies enabling us to control the beginnings of human life are altering the character of human procreation and human life; they therefore raise a number of broader ethical concerns that make this type of technology even more problematic than others.

From the diagnostic survey, the report concludes that the existing regulatory mechanisms are insufficient. There is no system of data collection, monitoring, and oversight in this area; there is only minimal direct governmental regulation; no mechanism for regulation of commerce in gametes and embryos; professional standards exist but are limited and not binding. When regulations exist, they are patchwork and deficient; for many important issues there are no regulations at all.

After these observations, one is well primed for the general conclusion that new regulatory institutions and mechanisms will be necessary.

But this is not the council’s conclusion. In fact, the report addresses the question regarding regulation with two fairly modest recommendations. First, it is necessary to obtain more additional information; crucial data are lacking. Therefore, recommendations are given for data gathering, reporting, and improved self-regulation. For example: the report recommends funding a longitudinal study of the impact of assisted reproductive technologies on the health and development of children born with their aid. This is an important recommendation, since many attempts to set up this type of studies have suffered from lack of interest from funding organization.

Second, the council proposes, not major new regulatory institutions or significant changes in existing regulatory institutions, but only a handful of interim measures focused on a small number of “boundary-crossing practices,” such as prohibiting the production of a hybrid human-animal embryo.

These modest recommendations are remarkable. It is not clear how more data will affect or facilitate the future regulation of biotechnologies. When in five years the requested data are available, it will be highly unlikely that the information will change the moral situation and will help to resolve the ethical quandaries. This result flows from the moral position taken by the council itself. The report repeatedly argues that assisted reproduction is “a most unusual branch of medicine” that, because it involves the production of a new child, needs special attention (and protection).

Why is the council not formulating recommendations more in line with its own ethical analysis? There are two reasons, only briefly articulated in the report. First, the development of science should be innovative and creative, and therefore it is by definition difficult to control. On the other hand, biotechnologies not only provide benefits but also imply harms; they also raise social questions, since they increasingly serve non-medical goals (“the perfect child,” “the ageless body”). They are therefore characterized as “promising but morally challenging” (p. xvii). In balancing the promises and challenges, the council decides in favor of the promises; regulation might have a chilling effect on the advance of science. The precautionary approach, usually defended in European reports, is not advocated, although precisely on the basis of the ethical concerns outlined by the council and the significance it gives to these concerns, such an approach could be justified.

The second reason for the modesty of the recommendations is the political context. The council is working amidst acute diversity on moral issues. Only limited and targeted measures will find support “on all sides,” yet the primary purpose of the report is to find genuine common ground. This also explains the emphasis on obtaining additional data. This is a first step “in a continuing national conversation.” Who can object to having more information? But in fact, the common ground, even with the extensive and careful factual diagnosis provided by the council, is rather limited and small.